

REMARKS/ARGUMENTS

DISCUSSION OF DRAWING

In response to the objection of the drawings as failing to comply with 37 CFR 1.84(p)(5) because they include reference character(s) not mentioned in the specification, the specification has been amended to include a description of reference characters "86", "88", and "92". No new matter has been added to the specification. Accordingly, withdrawal of the objections to the drawings is respectfully requested.

DISCUSSION OF SPECIFICATION

The specification has been amended in response to the objection of the drawings as failing to comply with 37 CFR 1.84(p)(5). In particular, on page 10, line 4, and on page 10, line 24, the following sentences have been respectively added: -The sensing circuits, 82 and 84, in turn, receive control signals over signal lines, 86 and 88, from the microcontroller 60.-- and --The data acquisition system 90 may receive control signals from the microcontroller 60 over control signal line 92.--. No new matter has been added to the specification because the control signals are clearly illustrated in Figure 2. Accordingly, acceptance of the amendments to the specification is respectfully requested.

In response to the objections of the specification, the following amendments have been made: page 16, line 16, "peak-proof" has been replaced with --leak-proof--; and page 17, line 15, "Tecothane" has been replaced with --TECOTHANE polyurethane-based biomedical elastomer from Thermedics--. Accordingly, withdrawal of the objections to the specification is respectfully requested.

The specification has been amended to correct an inadvertent typographical error. On page 13, line 19, "wall.." has been replaced with --wall.--. Acceptance of the amendment to the specification is respectfully requested.

DISCUSSION OF CLAIMS

In the Office Action, claims 10 and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the Office Action, claims 1, 6-17, and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,556,421 to Prutchi et al.

In the Office Action, claims 2-5 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Prutchi et al. in view of U.S. Patent No. 5,871,513 to Taylor et al.

In response thereto, claim 16 has been cancelled and claims 10, 13, and 19 have been amended. Accordingly, claims 1-15 and 17-19 are now pending. Following is a discussion of the patentability of each of the pending claims.

Preliminary Matter

During a telephone conversation with Steven Mitchell on February 13, 2006, a provisional election was made to prosecute the invention of Group I (claims 1-19). Affirmation of this election is made by the Applicants. Claim 20 is withdrawn from further consideration by the Examiner as being drawn to a non-elected invention.

In response to the rejection of claims 10 and 19 under 35 U.S.C. §112, second paragraph, the following amendments have been made: claim 10, line 2, "comprising" has been replaced with --consisting of--; and claim 19, line 2, "comprising" has been replaced with --consisting of--. Accordingly, withdrawal of the rejection of the claims under 35 U.S.C. §112, second paragraph, is respectfully requested.

Independent Claim 1

Claim 1 recites an implantable electronic device comprising a metal housing defining a leak-proof-sealed housing chamber, an optically-transmissive optical element connected to the housing and defining a leak-proof-sealed transducer chamber external to the housing and hermetically isolated from the housing

chamber, electronic circuitry contained within the housing chamber, and an optical transducer within the transducer chamber and connected to the circuitry.

The Prutchi et al. reference is directed to an implantable medical device having a container housing a power source and circuitry and further comprising a header portion that is molded or glued to the container housing. In the embodiment illustrated in Figure 3, an oximetry sensor (70) is encapsulated within the header (20). Among the objects of the Prutchi et al. reference is to provide an implantable device that would not require significant additional retooling for manufacturing. Column 5, lines 24-36, states the following: "because the invention takes advantage of a header such as that typically employed in present day pacemakers, the tried-and-true arrangement used in sealing conventional pacemakers may also be used when implementing the present invention. Likewise, no specialized housing or container for the implantable device circuitry is required when practicing the invention. Instead conventional components and manufacturing techniques may be employed, and no additional interfaces are created which require complicated or costly seal designs."

The Prutchi et al. reference does not disclose or suggest an implantable electronic device comprising an optically-transmissive optical element connected to a housing and defining a transducer chamber external to the housing and hermetically isolated from a housing chamber, wherein an optical transducer is within the transducer chamber and connected to electronic circuitry contained within the housing chamber. According to *Marriam Webster's Collegiate Dictionary* (Tenth Edition), the word "chamber" is defined as "a natural or artificially enclosed space or cavity," and the word "cavity" is defined as "an unfilled space within a mass; esp: a hollowed-out space." As stated previously with regards to the embodiment illustrated in Figure 3, the Prutchi et al. reference discloses a conventional header that is molded or glued to the container housing. As such, it appears that the oximetry sensor is placed within a mold, and the mold is filled with a polymer to encase the oximetry sensor. Thus, the polymer completely contacts the external surface of the oximetry sensor such that the header does not include a chamber (enclosed space or cavity).

The Taylor et al. reference is directed to centerless grinding methods and corresponding devices such as feedthroughs for implantable medical devices. In the various embodiments, the implantable medical device has a hermetically sealed housing containing circuitry. The circuitry is coupled to components external to the housing via a feedthrough having a centerless ground pin (25).

The Taylor et al. reference does not disclose or suggest an implantable electronic device comprising an optically-transmissive optical element connected to a housing and defining a transducer chamber external to the housing and hermetically isolated from a housing chamber, wherein an optical transducer is within the transducer chamber and connected to electronic circuitry contained within the housing chamber. The Taylor et al. reference is directed to providing a hermetically sealed housing chamber containing circuitry and coupling the circuitry to external electronic components via feedthroughs. Nowhere does the Taylor et al. reference disclose or suggest that the external electronic components are housed within a chamber that is hermetically isolated from the housing chamber.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2-12

Claims 2-12 depend from claim 11 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Furthermore, the Prtuchi et al. reference does not disclose or suggest what is recited in claim 5 of the present application: an optically-transmissive optical element that is hermetically sealed to the closure element. According to the specification of the present application, prior art devices employ emitters and detectors outside the device housing, but encapsulated by a transparent epoxy material that forms the device header. These suffer the disadvantage that the emitter and detector components are vulnerable to intrusion of body fluids, because an epoxy encapsulation is inadequate to provide a seal against such intrusion. Accordingly, such components are specially selected or manufactured to ensure

that they are formed of biocompatible materials that are not degraded by body fluids, and which do not degrade harmful materials as a result of such fluid contact that may leach back to body tissues and cause harm. This concern includes exposed lead wires, any required insulation, and materials used for soldering or welding. Conventional cost-effective LED lamps are further believed not to be hermetic, so that internal components must also be selected for biocompatibility, and incur the risk that degradation or failure may occur upon incursion of body fluids.

Claim 5 of the present application addresses these concerns by having a conventional metal housing defining a housing chamber that contains electronic circuitry and further having a hermetically sealed transducer chamber that is external to the housing chamber. As stated previously, one of the objectives of the Prutchi et al reference is to provide a header that is typically employed in present day pacemakers, the tried-and-true arrangement used in sealing conventional packers. Thus, the oximetry sensor is vulnerable to intrusion of body fluids because the header encapsulation does not provide a hermetic seal against such intrusion.

The Taylor et al. reference does not disclose or suggest an optically-transmissive optical element that is hermetically sealed to the closure element. As stated previously, the Taylor et al. reference is directed to providing a hermetically sealed housing chamber containing circuitry, but nowhere are external electronic components housed within an additional hermetic chamber.

Independent Claim 13

Claim 13 recites an implantable electronic device comprising a device housing defining a hermetically sealed housing chamber, an electronic cardiac rhythm-sensing circuitry within the housing chamber, an optical emitter and an optical detector connected to the circuitry and positioned outside of the housing, and an optically-transmissive optical element enclosing the emitter and detector with a hermetic seal.

For at least the same reasons discussed previously with regards to claim 5, it is respectfully submitted that claim 13 is in condition for allowance.

Dependent Claims 14, 15, and 17-19

Claims 14, 15, and 17-19 depend from claim 13 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

CONCLUSION

Applicant respectfully submits that the present application is in condition for allowance. If the Examiner believes a telephone conference would expedite or assist in the allowance of the present application, the Examiner is invited to call Steven M. Mitchell at (408) 522-6101.

Pursuant to 37 C.F.R. 1.136(a)(3), Applicant hereby requests and authorizes the U.S. Patent and Trademark Office to (1) treat any concurrent or future reply that requires a petition for extension of time as incorporating a petition for extension of time for the appropriate length of time and (2) charge all required fees, including extension of time fees and fees under 37 C.F.R. 1.16 and 1.17, to Deposit Account No. 22-0265.

Respectfully submitted,

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